K080052

OCT 02 2008

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stryker®

Instruments

510(k) Summary

Device Sponsor:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700 ext4233 (f) 269-324-5412
Registration No.:	1811755
Trade Name:	Stryker ESSx with Navigation Mount
Common Name:	Surgical ENT Drill with Accessories
Classification Name:	Drill, Surgical, ENT (electric or pneumatic) including Handpiece
Equivalent to:	K011381 Stryker Hummer IV MicroDebrider System K030343 Diego Powered Dissector Handpiece with Starlink Image Guided Adapter Mounting Interface K041523 XPS 3000 System
Device Description:	The Stryker ESSx with Navigation Mount is an electric, high-speed instrument system consisting of a motor (handpiece), hoses, and a variety of attachments and cutting accessories. The handpiece will operate with FDA cleared Stryker Navigation Systems. The Navigation feature will serve as a secondary verification to the tips position which is obtained through visual means typically with use of an endoscope.
Indications for Use:	The Stryker ESSx with Navigation Mount is to be utilized for Functional Endoscopic Sinus Surgery (FESS) for the incision of soft and osseous tissue in the sinus cavities, open plastic, reconstructive and aesthetic surgery of the Head and Neck. When used in conjunction with the Stryker Navigation/Tracker System, the device will enhance the surgeon's ability to localize anatomical landmarks (intraoperatively).
Substantial Equivalence (SE) Rational:	The Stryker ESSx with Navigation Mount has the same intended use, technological characteristics and navigated operating mechanism as compared to the predicate devices: the Diego Powered Dissector Handpiece with Starlink Image Guided Adapter Mounting Interface (K030343) and the Xomed XPS 3000 System (K041523). The Stryker ESSx with Navigation Mount has the same intended use as the Stryker Hummer IV MicroDebrider System (K011381).
Safety and Effectiveness:	Based upon the comparison to the predicate devices, the Stryker ESSx with Navigation Mount is substantially equivalent to legally marketed devices.

Submitted by: Valerie Franck
Senior Regulatory Affairs Representative

Valerie Franck
Signature

Date submitted: 9/30/08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

Stryker Corp.
c/o Valerie Franck
4100 East Milham Ave.
Kalamazoo, MI 49001

Re: K080052
Trade/Device Name: Stryker ESSx with Navigation Mount
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose and Throat (electric or pneumatic) surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: September 12, 2008
Received: September 15, 2008

Dear Ms. Franck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K080052

Device Name: Stryker ESSx with Navigation Mount

Indications for Use

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Prescription Use __X__ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K080052

Prescription Use X
(Per 21 CFR 801.109)